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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/743,762 | 05/14/2001 | Cecilia Larsson | 1547/00275 | 7301 |

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--|--|
| Office Action Summary | Application No. 09/743,762 | Applicant(s) LARSSON ET AL. <i>CH</i> | |
| | Examiner William H. Matthews (Howie) | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2-23-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2-23-04 have been fully considered but they are not persuasive.
2. Applicant contends NGK teaches away from a bioresorbable composition including calcium phosphate granules because of the example beginning at page 13/19 of NGK. The examiner disagrees because NGK clearly discloses on page 7/19 multiple calcium phosphate compounds which may be used, most notably hydroxyapatite $\text{Ca}_5(\text{PO}_4)_3\text{OH}$. Furthermore, the description on page 15/19 of a reusable device is described as an optional feature, and therefore any combination with Cassidy would not derive an inoperable device. NGK does not describe bioresorbable or non-bioresorbable as a requirement for operability.
3. With regard to moldable, injectable, Examiner maintains that the composition disclosed by NGK, when admixed with water, is moldable and the third paragraph of page 16/19 discloses an injectable compound. Cassidy is not relied upon for moldable or injectable compositions.
4. With regard to Larsson, Applicant contends the references are not combinable because liquid phases of Larsson are not combinable with the rigid structures of either NGK or Cassidy. Examiner disagrees because both Cassidy and NGK have liquid phases which are both injectable.

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Specification

1. The specification is objected to because of references listed in the specification and not in an information disclosure statement. All references listed in the specification should be included in an information disclosure statement. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 31-40,43-50,52-54,56 are rejected under 35 U.S.C. 103(a) as being unpatentable over NGK Spark Plug Co Ltd (JP 2198560) in view of Cassidy et al. US PN 6,280,474. Please note the supplied translation of JP 2198560.

4. NGK discloses in pages 6-16 (of the translation) a bone composition comprising the claimed forms of calcium phosphate, lipids, biologically active agents such as tissue promoting factors, and phosphatidyl choline or sphingomyeline. NGK lacks the express written disclosure of including a glycosaminoglycan such as sodium hyaluronic acid or that the calcium phosphate granules have a diameter of 0.05-5mm. Cassidy et al. teaches in columns 11-12 bone implant compositions comprising calcium phosphate granules having a diameter of 0.05-5mm and sodium hyaluronate to aid in shape retention of the implant during rehydration. Therefore it would have been obvious to

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one of ordinary skill in the art at the time of the invention to modify the device disclosed by NGK by using calcium phosphate granules having a diameter of 0.05-5mm and sodium hyaluronate to aid in shape retention of the implant during rehydration.

5. Claims 41,42,51, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over NGK Spark Plug Co Ltd (JP 2198560) in view of Cassidy et al. US PN 6,280,474 as applied to claims 31 and 40 above, and in further view of Larsson et al. US PN 5,196,201.

The bone composition taught by NGK as modified by Cassidy et al. meets the structural limitations of claims 41,42,51, and 55 but lacks the express written disclosure of the lipid in a lamellar floating crystalline phase and the specific ratios between the lipid to water based liquid and calcium phosphate granules to lipid. Larsson et al. teaches in lines 61 of col. 6 through line 31 of column 8 a bone composition having the specific ratios and lipid in a lamellar floating crystalline phase in order to provide a desired consistency. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the composition disclosed by NGK, as modified by Cassidy et al. above, to further included the specific ratios and lipid phase of claims 41,42,51, and 54 in order to provide a desired consistency.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM

WHM

May 24, 2004

CZ

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700